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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/474,677	12/09/99	SHARMA	Y 35284-03200(

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1644	5

DATE MAILED: 06/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/474,677	Applicant(s) Sharma
	Examiner Mary B. Tung	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 14, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-31* is/are pending in the applica

4a) Of the above, claim(s) *4, 5, and 21-31* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3 and 6-20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-27 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that the Examiner has not shown that examining the entire subject matter of the claims would constitute a serious burden under MPEP § 803. However, as stated in the restriction requirement, because these inventions have acquired a separate status in the art because of their recognized divergent subject matter and classifications, and because a non-patent literature and/or sequence search of any or these three distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner.

2. Group II, claims 28-31 are withdrawn from further consideration by the Examiner, 37 C.F.R. 1.142(b), as being drawn to non-elected inventions.

3. Applicant has further elected in Paper No. 4, the species of a viral infection, and further, a retrovirus. Claims 1-3 and 6-20 are readable on the elected species. Claims 4, 5 and 21-27 are patentably distinct and are accordingly held to be withdrawn from further consideration under 37 C.F.R. 1.142(b).

4. The Applicants traverse that the Examiner has not established that the "species-restricted subject matter" constituted a burden on the Examiner. However, this argument is not found persuasive because the Examiner need only establish that the inventions are patentably distinct in a species election and that being a "serious burden" is not the proper standard for a species requirement. See MPEP 806.04(a)-(i).

5. The requirement is still deemed proper and is therefore made FINAL.

Priority

6. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application 60/114,540, upon which priority is claimed, was filed more than one year subsequent to the filing of the instant application.

Sequence rules:

CRF Correction:

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2).

However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

8. Sequences are disclosed in the specification on page 11, line 14. Applicants are required to submit a disk and paper copy of the sequences according to the attached "Notice to Comply with the Sequence Rules." Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 C.F.R. 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Claim Rejections - 35 U.S.C. § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-3 and 6-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented

11. The Applicants disclose experiments that identify the active substance as *N*-glycoylneuraminic acid, a sialic acid not found in human primates. However, Noguchi, et al. *(J. Biochem. 117(1):59-62, Jan 1995)* teach that *N*-glycoylneuraminic acid, produced by CHO cells are the target of an immune response by Hanganutziu-Deicher antibodies (see the abstract) and that these antibodies are found in humans (see page 61, col. 2). The recitation of claim 1 of a method for preventing a retroviral infection is not enabled in light of **the state of the prior art** reveals that there is no cure, that even with the 'newer' nucleoside analog and protease inhibitor therapy, that "potent activity in most recipients up to 1-2 years, and that new therapies reduce viral burden, but is not efficiency of transmission (see *Johns Hopkins 1997 Guide to Medical Care of HIV Patients*, pages 23 and 24). Thus, the retrovirus, HIV is an intractable disease in which no cure or effective treatment past 1-2 years after treatment initiation was known in 1997. The **relative skill of those in the art** is high, comprising medical practitioners

with M.D. or M.D./Ph.D. degrees and researchers with M.D., Ph.D. or M.D./Ph.D. or equivalent degrees, both groups typically having over 3-6 years in postdoctorate training or residencies. Even considering the high skill of those in the art, there is a high degree of **unpredictability in the art** concerning HIV therapies and still unknown problems and mechanisms such as viral latency (see Grant and Abrams; Perrin and Hirschel, page 88, col. 2; Medina, et al., Introduction; and Bolognesi; page 39) and which therapies should be used (see Perrin and Hirschel, page 87). Therefore, is would be unpredictable as to whether the claimed therapy in human would be successful, given the known antigenicity in humans.

12. Given the nature of the invention, the recognition in the prior art of the intractable and unpredictable nature of the treatment of HIV, the high skill of those in the art, the lack of properly-controlled working examples and the lack of direction or guidance presented, it would take an **undue amount of experimentation** for one of skill in the art to practice the invention as disclosed.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

14. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

15. Claim 16 fails to further limit claim 1, which renders the claim indefinite.

Claim Rejections - 35 U.S.C. § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (f) he did not himself invent the subject matter sought to be patented.

17. Claims 1-3 and -20 are rejected under 35 U.S.C. 102(f) because the Applicant did not invent the claimed subject matter.

18. The Applicants submitted Exhibit 5 on April 25, 2000 in parent application 09/015,830. It is noted that Exhibit 5 from Southern Research Institute was addressed to Dr. Steven Turk, Project Officer NIH, NIAID, DAIDS, TRP, DDCSB. It is further noted that on page 3 of the response submitted on April 25, 2000, Paper No. 18, in the '830 application that the Applicants stated that Exhibit 5 demonstrates the anti-HIV properties of N-glycolylneuraminic acid, which the Applicants describe as the active

ingredient of the baboon cell extract, and is the subject matter of the claimed invention. Dr. Turk was not named as a co-inventor, nor was the NIH listed as an assignee in the application. Figure 7 of the '830 application lists a person by the name of Trevor O'Neil associated with the SDS Page gel. Therefore, the inventorship of the instant application is not clear, especially given the submission of the small entity declaration that no assignee exists. It is noted that the Statement claiming small entity filed June 19, 1998 in the '830 application does not have the declaratory statement under Section 1001 of Title 18 marked. It is required that the Applicants clarify the inventorship of the instant application.

Conclusion

19. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

20. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

June 22, 2001
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

MARY BETH TUNG, PH.D
PATENT EXAMINER

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other:

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
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